REMARKS

Claim Status

Claims 36, 38, 41-43, 46 and 48 are pending in the present application. No additional claims fee is believed to be due.

Claims 1-35, 37, 39, 40, 44, 45, and 47 have been previously canceled without prejudice.

Rejection Under 35 USC §103(a)

Claim 36, 38, 41-43, 46 and 48 are rejected under 35 USC §103(a) as being unpatentable over US Patent No. 6,682,747 to Turck et al. ("Turck") as evidenced by the Univar product sheet ("Univar") or alternatively unpatentable over US Patent No. 5,112,604 to Beaurline ("Beaurline") in view of Turck as evidenced by Univar.

The Examiner asserts that Turck discloses a process for preparing an oral liquid preparation having from 0.1% to 5% highly dispersed silicon dioxide, which can be Aerosil 200. The Examiner acknowledges that Turck does not disclose the particle size of the silicon dioxide, but asserts that Univar provides particle size and surface area of the silicon dioxide. Therefore, the Examiner asserts that the amount and particle size disclosed by Turck are within the Claimed range of silicon dioxide.

The Examiner also asserts that Turck discloses NSAIDs as the active agent, and suggests an aqueous buffer system for the suspension. Additionally ,the Examiner asserts that Turck discloses citric acid monohydrate in the buffering system. The Examiner acknowledges that Turck does not disclose an amount of citric acid or water, however, the Examiner asserts that it would have been obvious to employ suitable amounts of citric acid and water to obtain an optimal aqueous buffer system.

The Examiner asserts that the Applicants' claimed element, that the mixture forms a gel-like mixture upon contact with a mucosal surface, is an intended use and that because Turck discloses all of the claimed components the burden is shifted to the Applicants to show that gel formation does not occur with the composition of Turck.

Alternatively, the Examiner asserts that Beaurline discloses aqueous suspension formulations having a drug, a wetting agent, a hydrocolloid gum, colloidal silicon

dioxide, antifoaming agent, citric acid, water and other components. The Examiner asserts that Beaurline discloses anti-tussive and anti-inflammatory compositions similar to those of the present invention. Additionally, the Examiner asserts that Beaurline discloses an amount of citric acid that falls within the Claimed range.

The Examiner acknowledges that Beaurline does not disclose particle size of the silicon dioxide, but asserts that Beaurline discloses 'colloidal' silicon dioxide which is defined in the present Specification. Additionally the Examiner asserts that Beaurline references the use of Aerosil 200 which the Examiner asserts is described in Univar with respect to particle size.

The Examiner also acknowledges that Beaurline does not disclose the amount of water in the composition, but asserts that the Examples of Beaurline discloses simple syrup preparations which would contain water. Therefore, the Examiner asserts that, absent unexpected advantage with the Claimed high amounts of water, it would have been obvious to include the appropriate amount of water to the composition of Beaurline to prepare an oral liquid composition of desired viscosity.

The Examiner acknowledges that Beaurline only teaches 0.2 to 2% silicon dioxide, versus the Claimed 3% - 20% and 5% - 15%. However, the Examiner asserts that Turck discloses a composition stabilized by the addition of a highly dispersed silicon dioxide in a range of from 0.1% - 5% such that the disclosure of Turck overlaps the Claimed range. The Examiner asserts that Turck discloses that the addition of a hightly dispersed colloidal silicon dioxide in the disclosed amounts stabilizes the composition *without increasing viscosity*, and retains the ability to reconstitute *without causing a gel-like substance.* Thus, the Examiner asserts that both Turck and Beaurline desire a stable oral aqueous suspension without too much viscosity, and that Turck discloses that small amounts of silicon dioxide achieve such. Therefore, the Examiner asserts that it would have been obvious to include silicon dioxide in an amount from 0.1% - 5% with an expectation to stabilize the composition *without forming a gel-like substance.*

The Examiner asserts that while neither Turck nor Beaurline disclose the ability of the compositions therein to form a gel, the property is an intended use, and the cited documents render the Claims obvious, and hence the ability to form a gel obvious. The Examiner asserts that such is substantiated by the Applicants' previous arguments that a

"gel" describes the substance resulting from the combination of mucin/saliva and the Claimed composition, and that because Turck and/or Beaurline renders the composition obvious, the formulation resulting from the teaching of the cited documents does result in a gel upon acting with mucin/saliva.

The Applicants respectfully traverse the rejection and submit that the Examiner has not established a *prima facie* case of obviousness. See MPEP § 2143.01. Even in light of *KSR v. Teleflex* 127 S.Ct. 1727 (2007) ("*KSR*"), in order for an obviousness rejection to stand, there should at least be some need or predictability in the achieved result, considering the common sense of one of ordinary skill in the art.

Turck discloses suspensions of NSAIDs. The NSAID is suspended such that it has very little solubility so that the suspension has no perceptible taste of its own, and the suspension contains a small amount of highly dispersed silicon dioxide. The suspension of Turck has a particular structure that *does not lead to <u>any</u> gel-like thickening of the dispersion medium, but rather produces a low viscosity pourable suspension.* The suspension also contains from about 0.05% - 2% of water soluble cellulose ether. Turck fails to disclose, teach or suggest the total amount of water in the composition, or effect or benefit thereof, and also does not disclose, teach or suggest citric acid or any amount thereof. Thus, contrary to the Examiner's assertion, Turck does *not* disclose or teach all of the Claimed components.

Furthermore, there is no teaching or suggestion that would have led one of skill in the art to the Claimed methods or compositions which have particular properties. With respect to the properties of the Claimed compositions, the Examiner asserts that the Applicants must show that gel formation does not occur with the composition of Turck. The evidence sought by the Examiner is found in Turck itself. At column 3, lines 61-64, Turck describes that the particular siliod structure described "does not lead to any gel-like thickening of the dispersion medium but rather produces a low viscosity pourable suspension". Thus, Turck not only does not disclose gel formation but Turck specifically and *explicitly* teaches *away* from *any* formation of a gel, and teaches that the compositions described therein do not and would not form gels. Therefore, one of skill in

art would be explicitly led away from forming a gel and any desirability, use or expectation of success for forming or using such a gel because Turck specifically directs those of skill in the art *away* from forming an gel, or having *any* gel-like thickening of the composition. Turck teaches only a low viscosity pourable suspension. Therefore, Turck teaches away from the Claimed composition with particular amounts of silicon dioxide, citric acid and water which yield the gel-like mixture upon contact with mucin/saliva, regardless of whether the range and/or particle size of one component thereof, overlaps the Claimed range of said component. Because Turck explicitly teaches away from the present invention, Turck can not properly be cited or combined with the other cited documents as a basis for rejection.

Furthermore, a gel, even as defined in the present specification, as cited by the Examiner, is a *substance* and/or property of a substance and *not* a *use*, as asserted by the Examiner. Examples of *uses* of the gel-like substance and property are provided in the present specification - uses such as retention on the mucosa, coating of the mouth, esophagus, etc. However, the gel-like substance itself is not a use, contrary to the Examiner's assertion. Thus, the Applicants' statement, cited by the Examiner, that a "gel" describes the *substance* resulting from the combination of mucin/salia mixture and the composition, actually contradicts the Examiner's position that the gel is a use. The Applicants' statement, and the specification show that the gel-like substance is a *substance*.

Beaurline, with particular respect to the amount of silicon dioxide, discloses a maximum of 2% silicon dioxide. Beaurline desires to create an aqueous pharmaceutical suspension that maintains the medicament in suspension for a prolonged period of time without shaking. Beaurline does not disclose, teach, suggest or provide any motivation or expectation of success for creating or forming a gel. Beaurline does not provide any need or motivation for adding greater amounts of silicon dioxide, or for creating a gel. Furthermore, a gel, even as defined in the present specification, cited by the Examiner, is a *substance* and/or property of a substance and *not* a *use*, as asserted by the Examiner. Examples of *uses* of the gel-like substance and property are provided in the present

specification - uses such as retention on the mucosa, coating of the mouth, esophagus, etc. However, the gel-like substance itself is not a use, contrary to the Examiner's assertion.

Additionally, Beaurline does not disclose, suggest or provide motivation or expectation of success for creating a composition or method of administering a *liquid aqueous mucoretentive composition* that forms a gel-like mixture upon contact with a mucosal surface as recited in the Claims. As noted above and defined in the Specification at page 7, beginning at line 10, the term "gel" describes *the substance* resulting from the combination of mucin/saliva mixture and the formulation of the present invention. Beaurline does not disclose, suggest or provide motivation or expectation of success for such a *composition* that would form a gel-like *substance* upon contact with a mucosal surface as recited in the present Claims. The objective of Beaurline is to create a stable suspension, *not* to create a gel-like substance upon contact with a mucosal surface and thus Beaurline provides no motivation for, or expectation of success in, creating or using a *liquid aqueous mucoretentive composition* that forms a gel-like mixture upon contact with a mucosal surface.

Finally, the Applicants assert that unexpected advantages have been disclosed in the present Specification. For example, see page 2, lines 10-21 wherein the benefits of a flowable liquid that becomes a viscous gel upon contact with mucosal surfaces are discussed. See also page 6, lines 28-33 wherein the conversion to a viscous gel-like mixture is discussed. None of the cited documents disclose, suggest or provide motivation or expectation of success for creating such a composition, or method, and Turck, in particular, teaches away from such a composition.

Assuming *arguendo* Turck and/or Univar and/or Beaurline were combined, one would still have fallen short of the Applicants' claimed invention, perhaps to have arrived at a liquid suspension for NSAIDs that contains small amounts of silicon dioxide, but which specifically would not form a gel. However, one would not have arrived at the presently claimed invention.

Therefore, the Applicants respectfully submit that none of the cited documents, whether taken alone or in combination, discloses, teaches, suggests or provides motivation or expectation of success for the invention as presently claimed. Furthermore, the Applicants assert that Turck is an improper reference and can not be used as a basis for the rejection because Turck explicitly teaches away from *any* gel-like thickening of the compositions therein.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied documents. In view of the foregoing, reconsideration of this application, and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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